

WHAT IS CLAIMED:

1. An assembly for trapping arterial plaque against a vascular wall, comprising:

a radially outwardly deformable, tubular sheath having a proximal end and a distal end, said sheath to be introduced intravascularly and expanded against the vascular wall to trap the plaque therebetween.

2. The assembly of claim 1, further comprising:

a flexible elongated tubular member with an inner lumen extending therethrough from a proximal end of the tubular member to a distal end of the tubular member that is attached to the proximal end of the sheath.

3. The assembly of claim 2, wherein the tubular member is a catheter.

4. The assembly of claim 3, wherein the sheath is an integral part of the distal end of the catheter.

5. The assembly of claim 2, wherein the tubular member has a plurality of perforations formed near the distal end to allow fluid communication therethrough between the outside of the tubular member and the inner lumen.

6. The assembly of claim 1, wherein the sheath is comprised of a material selected from the group of materials consisting of polymers, cross-linked materials, and composites.

09085458-061901  
TOP SECRET

7. The assembly of claim 6, wherein the sheath material has a yield strength of between 50 psi and 300 psi.
8. The assembly of claim 7, wherein the sheath material has a break point tensile strength of over 2000 psi.
9. The assembly of claim 1, further comprising:  
a radially outwardly deformable, tubular member disposed within the sheath between the distal end and the proximal end of the sheath to be expanded together with the sheath against the vascular wall.
10. The assembly of claim 9, wherein the deformable member is comprised of a material selected from the group of materials consisting of metals and thermoplastics.
11. The assembly of claim 9, wherein the deformable member is a wire mesh.
12. The assembly of claim 9, wherein the deformable member is a stent.
13. The assembly of claim 9, wherein the deformable member is a wire coil.
14. The assembly of claim 9, further comprising:

a flexible, elongated tubular member having an inner lumen extending therethrough from a proximal end of the tubular member to a distal end of the tubular member attached to the proximal end of the sheath to introduce the sheath with the  
5 deformable member intravascularly.

15. The assembly of claim 14, wherein the tubular member is a catheter.

16. The assembly of claim 15, wherein the sheath is an integral part of the distal end of the catheter.

17. The assembly of claim 14, wherein the tubular member has perforations formed near the distal end to allow fluid communication therethrough between the outside of the tubular member and the inner lumen.

18. The assembly of claim 9, wherein the sheath is comprised of a material selected from the group of materials consisting of polymers, cross-linked materials, and composites.

19. The assembly of claim 19, wherein the sheath material has a yield strength of between 50 psi and 300 psi.

20. The assembly of claim 19, wherein the sheath material has a break point tensile strength of over 2000 psi.

0905456 "051904

21. The assembly of claim 9, wherein the deformable member is formed from a radiopaque material.

22. The assembly of claim 9, wherein the deformable member is formed from a shape memory alloy having a compressed state for placing within the unexpanded sheath and an expanded state for anchoring the sheath against the vascular wall, and exhibiting a radially outward expansive force when in the compressed state.

23. The assembly of claim 22, wherein the resistance to elastic deformation of the sheath is greater than the expansive force exhibited by the deformable member.

24. The assembly of claim 23, wherein the resistance to elastic deformation of the sheath is between 1 percent to 5 percent greater than the expansive force exhibited by the deformable member.

25. The assembly of claim 14, further comprising:  
a catheter disposed within the lumen of the tubular member with a balloon portion of the catheter lying within the deformable member to expand the deformable member together with the sheath against the vascular wall.

26. The assembly of claim 9, wherein the deformable member is embedded within the sheath.

27. The assembly of claim 26, wherein the deformable member is a wire coil.

28. The assembly of claim 26, wherein the deformable member is a stent.

29. A method for entrapping plaque particles against a vascular wall at a predetermined intravascular site, comprising the steps of:

providing a radially outwardly deformable, tubular sheath having a proximal end and a distal end;

5 providing an intravascular deployment catheter having a proximal end, a distal end, and a lumen extending therebetween;

attaching the sheath proximal end to the deployment catheter distal end;

introducing the deployment catheter into the vasculature;

10 advancing the deployment catheter through the vasculature to position the sheath at the intravascular site; and

expanding the sheath against the vascular wall at the intravascular site to trap the plaque therebetween.

30. The method of claim 29, wherein the sheath is formed as a unitary part of a distal tip of the deployment catheter.

31. The method of claim 29, wherein the step of providing an intravascular deployment catheter comprises providing an intravascular deployment catheter having a plurality perforations formed near the distal end of the deployment catheter to allow fluid communication between the outside of the deployment catheter and the  
5 deployment catheter lumen.

32. The method of claim 29, wherein the sheath is comprised of a material selected from the group of materials consisting of polymers, cross-linked materials, and composites.

33. The device of claim 32, wherein the sheath material has a yield strength of between 50 psi and 300 psi.

34. The method of claim 33, wherein the sheath material has a break point tensile strength of over 2000 psi.

35. The method of claim 29, comprising, prior to the step of introducing the deployment catheter, the further steps of:

providing a radially outwardly deformable, tubular member;

disposing the deformable member within the sheath; and wherein

5 the step of expanding the sheath comprises expanding the deformable member along with the sheath, the sheath contacting the vascular wall and the deformable member contacting the sheath.

36. The method of claim 35, wherein the deformable member is a wire mesh.

37. The method of claim 35, wherein the deformable member is a stent.

0905436-061501  
105190-9948860

[illegible]

45. The method of claim 43, wherein the deformable member is a wire coil.

46. The method of claim 29, comprising, following the step of expanding the sheath, the further steps of:

providing a delivery catheter having a proximal end and a distal end and a lumen extending therebetween;

5 providing a self-expanding intravascular device having a proximal end and a distal end and further having a compressed state and an expanded state;

placing the intravascular device in its compressed state within the delivery catheter distal end;

10 introducing the delivery catheter into the lumen of the deployment catheter;

advancing the delivery catheter through the lumen of the deployment catheter to position the distal end of the delivery catheter adjacent the distal end of the sheath;

15 partially retracting the delivery catheter to allow the distal end of the intravascular device to expand against the vessel wall at a location distal of the plaque at the intravascular site;

withdrawing the sheath proximally from the intravascular site to expose the distal end of the delivery catheter;

20 retracting the delivery catheter to allow the entire intravascular device to expand against the vessel wall at the intravascular site and trap the plaque therebetween;

withdrawing the delivery catheter from within the intravascular catheter; and

25 withdrawing the intravascular catheter and the sheath from within the vasculature.

47. The method of claim 46, wherein:



the steps of advancing the intravascular device out of the delivery catheter comprise withdrawing the delivery catheter proximally along the pusher rod to expose the intravascular device and thereby allow it to assume its expanded state.

49. The method of claim 48, wherein the stent is formed with a plurality of apertures, each aperture being no larger than 200 microns across when the stent is in the expanded state.

51. The method of claim 50, wherein the wire mesh is formed with a plurality of apertures, each aperture being no larger than 200 microns across when the wire mesh is in the expanded state.

the step of expanding the sheath against the vascular wall comprises partially expanding the sheath; and comprising, after the step of withdrawing the delivery catheter, the further steps of:

5 providing a balloon catheter;

inserting the balloon catheter into the lumen of the deployment catheter;  
advancing the balloon catheter to position the balloon within the  
intravascular device;

inflating the stent to further expand the intravascular device against the  
10 vessel wall and entrap the plaque therebetween; and  
withdrawing the balloon catheter from the deployment catheter lumen.

53. The method of claim 46, wherein the step of providing a delivery catheter  
comprises providing a delivery catheter with perforations formed near the distal end of  
the delivery catheter to allow fluid communication between the outside of the delivery  
catheter and the delivery catheter lumen.

54. An assembly for trapping arterial plaque against a vascular wall,  
comprising:

a deployment catheter having a proximal end, a distal end, and an inner  
lumen extending therebetween;

5 a radially outwardly, deformable, tubular sheath to be introduced  
intravascularly and expanded against the vascular wall to entrap the plaque  
therebetween, the sheath having a proximal end attached to the deployment catheter  
distal end, and a distal end;

a delivery catheter being axially movably disposed within the deployment  
10 catheter lumen and having a distal end and an inner lumen;

a self-expanding intravascular device disposed within the delivery  
catheter lumen adjacent the delivery catheter distal end;

an outer sheath disposed over the deployment catheter to receive the  
deformable sheath therein; and

15 a pusher rod axially movably disposed within the delivery catheter lumen  
proximal of the intravascular device.

000046-061901

55. The assembly of claim 14, further comprising:  
an outer sheath disposed over the tubular member to receive the sheath  
therein.

0909463 061904  
"061904" 0909463